Investigators Report Revimid(TM) Demonstrates Anti-Tumor Activity in Phase I/II Clinical Trials In Multiple Myeloma;

Celgene Corporation Will Significantly Expand Clinical Development of REVIMID

PR Newswire

December 11, 2001, Tuesday

Section: FINANCIAL NEWS

Length: 1053 words

Dateline: ORLANDO, Fla., Dec. 11

Body

Celgene Corporation (Nasdaq: CELG) -- Kenneth Anderson, M.D. from the Dana-Farber Cancer Institute at Harvard University and Bart Barlogie, M.D., Ph.D. from the Arkansas Cancer Research Center and their colleagues presented new clinical data at the 43rd annual meeting of the American Society of Hematology from two Phase I/II trials of REVIMID(TM) in refractory and relapsed multiple myeloma. The investigators reported that REVIMID demonstrated significant anti-tumor activity and was generally well tolerated in patients.

"These encouraging results continue to validate our pipeline of IMiD compounds and based on these data we will substantially expand the clinical development of REVIMID," said Sol J. Barer, Ph.D., President and Chief Operating Officer of Celgene Corporation. "Following discussions with the FDA, we plan to initiate two pivotal clinical programs for REVIMID in multiple myeloma and metastatic melanoma with over 1,000 patients in each program. Each program will be comprised of three pivotal trials, in both refractory and newly diagnosed stages of each disease."

Paul G. Richardson, M.D. presented data from an open-label safety clinical trial conducted at Dana-Farber. The study included twenty-four evaluable patients with rapidly advancing refractory multiple myeloma, sixteen of whom had failed thalidomide and all of whom had failed at least two prior regimens. Patients were treated with one of four doses of REVIMID: 5 mg/day, 10 mg/day, 25 mg/day or 50 mg/day. After 28 days, if tolerated and without disease progression, patients were permitted to continue on therapy.

Nineteen patients (79 percent) achieved stable disease or better and 63 percent of patients experienced a greater than 25 percent reduction in paraprotein. No dose limiting toxicities were observed within twenty-eight days at any dose level. In the extension phase of the trial, dose reduction was required for grade 3 thrombocytopenia and grade 3/4 neutropenia. Somnolence, constipation and neuropathy, common side effects of thalidomide, were not observed.

"REVIMID demonstrated anti-tumor activity in these very difficult to treat patients," said Dr. Richardson. "The therapy was generally well tolerated and may represent a new approach to the treatment of multiple myeloma."

Maurizio Zangari, M.D. from the Arkansas Cancer Research Center reported on the treatment of fifteen refractory multiple myeloma patients who participated in two clinical trials: a four week, open-label safety trial and an extension trial. In the first trial, patients received a daily dose of 5 mg, 10 mg, 25 mg, or 50 mg of REVIMID. If tolerated and without disease progression, patients entered an extension trial in which the dose could be adjusted. Eight patients (53 percent) experienced a greater than 25 percent reduction in paraprotein and one patient achieved a complete response. In the extension phase of the trial at higher doses, clinically significant, but manageable, reductions in both the granulocyte and platelet counts were observed.

"We are looking forward to advancing REVIMID based on its clinical activity and tolerability," said Dr. Zangari.

REVIMID has also completed the initial phase of a clinical trial in metastatic melanoma, and based on the results, the trial is being expanded with an additional 60 patients. Further studies are planned for REVIMID in anti-inflammatory diseases, in addition to a recently initiated congestive heart failure pilot trial.

The IMiDs are novel, small molecule, orally available analogs of thalidomide that are designed to be more potent and have demonstrated a better safety profile in clinical trials than the parent compound. Celgene's IMiDs have significantly greater immunological activity than thalidomide in in vitro studies. Data published in The Journal of Immunology demonstrated that IMiDs potently inhibit the inflammatory cytokines TNF-alpha and interleukin (IL)-1 beta while stimulating the anti-inflammatory cytokine IL-10. IMiDs were also reported in Blood to enhance T-cell proliferation and IL-2 production. REVIMID and the IMiD pipeline are covered by a comprehensive intellectual property estate of U.S. and foreign issued patents and pending patent applications including composition-of-matter, pharmaceutical composition and use patents.

About Multiple Myeloma

There are approximately 40,000 people in the United States living with multiple myeloma. It is the second most common blood cancer, with 14,000 new cases of multiple myeloma diagnosed each year in the United States. Incurable with conventional chemotherapy, multiple myeloma is a malignant cancer of the plasma cell, which is a type of white blood cell, found in many tissues of the body, but mainly in the bone marrow. As the cancer grows it destroys normal bone tissue, causing pain and crowding out normal cell production. There are nearly 11,200 deaths expected during 2001, according to the Multiple Myeloma Research Foundation and the American Cancer Society.

Celgene Corporation, headquartered in Warren, New Jersey, is an independent biopharmaceutical company engaged in the discovery, development and commercialization of small molecule drugs for the treatment of cancer and immunological diseases through gene regulation.

This release contains certain forward-looking statements which involve known and unknown risks, delays, uncertainties and other factors not under the Company's control, which may cause actual results, performance or achievements of the Company to be materially different from the results, performance or other expectations implied by these forward-looking statements. These factors include results of current or pending research and development activities, actions by the FDA and other regulatory authorities, and those factors detailed in the Company's filings with the Securities and Exchange Commission such as 10K, 10Q and 8K reports.

MAKE YOUR OPINION COUNT - Click Here

http://tbutton.prnewswire.com/prn/11690X51697372

SOURCE Celgene Corporation
CONTACT: Robert J. Hugin, Senior Vice President and CFO of Celgene Corporation, +1-732-271-4102

URL: http://www.prnewswire.com

Classification

Language: ENGLISH

Subject: BLOOD DISORDERS (90%); CANCER (90%); DISEASES & DISORDERS (90%); MEDICAL RESEARCH (90%); INVESTIGATIONS (90%); ONCOLOGY (89%); CLINICAL TRIALS (89%); RESEARCH INSTITUTES (78%); TALKS & MEETINGS (77%); NEUROLOGICAL DISORDERS & INJURIES (73%); SKIN CANCER (73%); EXECUTIVES (69%)

Company: CELGENE CORP (97%); DANA-FARBER CANCER INSTITUTE INC (92%); CELGENE CORP (97%); DANA-FARBER CANCER INSTITUTE INC (92%); Celgene Corporation HARVARD UNIVERSITY (84%); DANA-FARBER CANCER INSTITUTE (84%); DANA-FARBER CANCER

INSTITUTE (84%); HARVARD UNIVERSITY (84%); FOOD & DRUG ADMINISTRATION (56%); FOOD & DRUG ADMINISTRATION (56%); Celgene Corporation

Organization: HARVARD UNIVERSITY (84%); DANA-FARBER CANCER INSTITUTE (84%); DANA-FARBER CANCER INSTITUTE (84%); HARVARD UNIVERSITY (84%); FOOD & DRUG ADMINISTRATION (56%); FOOD & DRUG ADMINISTRATION (56%)

Ticker: CELG (NASDAQ) (97%); CELG (NASDAQ) (97%); CELG

Industry: PHARMACEUTICALS PRODUCT DEVELOPMENT (90%); ONCOLOGY (89%); CANCER DRUGS (89%); CLINICAL TRIALS (89%); ACADEMIC MEDICAL CENTERS (78%); CARDIOVASCULAR DRUGS (77%)

Person: SOL J BARER (59%)

Geographic: UNITED STATES (78%)

Load-Date: December 12, 2001

End of Document